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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/592,024	09/07/2006	Gert Nilsson	4007620-173753	9372

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EXAMINER	
BRUTUS, JOEL F	
ART UNIT	**PAPER NUMBER**
3777	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/592,024	NILSSON ET AL.	
	Examiner	Art Unit	
	JOEL F. BRUTUS	3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-22 and 36-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-22 and 36-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/28/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/16/2011 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 12, 14-15 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groner et al (US Pat: 5,983,120) stand alone or in view of Shih (US Pat: 6,061,176) in view of Godik (US Pat: 5,699,797) and further in view of Nilsson (US Pat: 5,361,769) and further in view Zinser et al (US Pat: 5,620,000).

Regarding claim 12, Groner et al disclose a method to perform in vivo analysis of blood vessels to determine blood parameters such as concentrations and blood cell counts [see column 5 lines 50-55]. Groner et al disclose an apparatus for detecting optical characteristics of an object, includes a light source for illuminating the object,

and detecting means for detecting reflected light that is reflected from the illuminated object [see column 5 lines 57-68]. Groner et al disclose a polarizer (or polarizer filter) is used to polarize light from the light source. Groner et al disclose the light source is monochromatic, polarized, or monochromatic [see column 5 lines 57-68]. Groner et al disclose the light source is used to illuminate the portion of the subject's vascular system to be imaged. The reflected light is captured by an image capturing means, an image analyzing means, such as a computer, is coupled to the image capturing means for carrying out scene segmentation, and blood characteristic analysis [see column 8 lines 55-68].

With regards to photosensitive array; Applicant discloses a photosensitive array may be a digital camera. Alternatively, conventional types of sensors producing analog signals are conceivable and may be connected to an analog/digital converter of conventional nature [see 0010, specification]. Accordingly, Groner et al disclose detecting means 2036 can be any device for detecting reflected light 2046; such as a photodetector, a photocell, photodiode or other device capable of detecting the reflected light intensity of reflected light 2046, a camera or camera array [see column 33 lines 37-45, column 8 lines 55-68, claims 4-6, 11-12 and fig 20].

Groner et al disclose quantitative analyses of blood cell components (red blood cells, white blood cells, and platelets) can be done and concentration measurements, blood cell counts can be made through the use of reflected spectral images of the vascular system and can be visualized and segmented into an analysis image [see

column 6 lines 1-20]. Groner et al disclose concentration measurements of red blood cells can be made directly from the images [see column 8 lines 33-43].

Groner et al disclose image separating means that separates the reflected image from image capturing means into multiple image portions [see column 5 lines 1-7] and analyzing the analysis image for a characteristic of the blood [see column 5 lines 12-15].

With regards to converting detected light to collected information of digital values; the backscattered lights are inherently converted into digital values since computer use digital values for processing and the computer is coupled to the detector means.

Nonetheless, Shih discloses an analog-to-digital converter to convert detected light into digital values with digits in an image card 6 by the microcomputer 4 and the images of circulation are directly displayed on the monitor 5 to enable measuring of microcirculation [see column 2 lines 1-10].

Further, Nilsson discloses a photodetector 9 detecting backscattered lights from body part into a signal processing 10 to convert the detected light to digital values [see column 4 lines 48-60].

With regards to computing device adapted to separate collected data into data matrixes representing red, blue and green colors, respectively; Groner et al disclose image micro vascular system can be imaged to produce an image, a difference between white and red blood cells in the blue and green portions of the visual spectrum [see column 17 lines 21-28]. Groner et al disclose image analyzing means or computer use hardware or software to segment image [see fig 2, column 29 lines 23-25]. It is well

known in the art that segmenting an image is separating the image into multiple portions as disclosed by Groner et al [see column 5 lines 1-7]. A software algorithm would determine red blood cell concentration [see figs 9, 14] from the multiple portions (or data matrices, emphasis added).

In the alternative, Zinser et al teach computer 32 collects a matrix MxN measured values [see column 5 lines 59-62] and a second matrix MxN of measured values which are subject to FFT Fourier transform [see column 8 lines 52-57] and matrices can be displayed on the screen of computer 32 as an image [see column 7 lines 10-17].

Nilsson discloses deliver measurement values to computer 7 to determine blood circulation [see column 4 lines 48-60]. Nilsson discloses a color monitor connected to computer 7 to display microcirculation in specific colors [see column 5 lines 1-8] which could be red, green and blue (emphasis added).

In addition, Godik discloses display microcirculation behaviors of physiological liquids are marked with the help of pseudo-colors [see column 12 lines 11-18] which could be red, green and blue (emphasis added).

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Groner et al with Shih, Godik, Zinser et al and Nilsson by using red, blue and green to display microcirculation; in order to increase visualization and because it's helpful in early diagnosis, medication instruction, and emergent treatment of cardiovascular diseases [see column 3 lines 34-45, Shih]. One skilled in the art at the time the invention was made would have been motivated to

computer 32 that separates data into MxN matrices and display matrices with red, green and blue; in or to accurately and precisely representing microcirculation.

Regarding claim 14, Groner et al disclose the plane of polarization of the second polarizer is 90 degree relative to a plane of polarization of the polarizer [see column 5 lines 45-50, 57-68 and see fig 20]. Groner et al also disclose polarizer 2034 provides polarization plane 2035 orthogonal to light source 2022 and illumination light 2038 and polarizer 2026 [see fig 20].

Regarding claim 15, Groner et al disclose a plane of polarization 2027 which is parallel in direction of polarized light 2038 from light source 2022 and polarizer 2026 [see fig 20 and column 33 lines 37-45].

Regarding claims 20-22, Groner et al disclose computer system 1600 can also include a communications interface 1624 that allows software and data to be transferred between computer system 1600 and external devices. Interface 1624 can be a modem, a network interface (such as an Ethernet card), a communications port, a PCMCIA slot and card, etc. Groner et al further disclose signals are provided to communications interface via a channel 1628 that carries signals and can be implemented using a phone line, a cellular phone link, an RF link and other communications channels [see column 29 lines 63-68, column 30 lines 1-10 and fig 16]

that is capable of transmitting the output data matrix using two separate mobile communications (cell phone, modem, internet, etc).

4. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Groner et al (US Pat: 5,983,120) stand alone or in view of Shih (US Pat: 6,061,176)in view of Godik (US Pat: 5,699,797) and further in view of Nilsson (US Pat: 5,361,769) and Zinser et al (US Pat: 5,620,000) as applied to claim 12 above and further in view of Crutchfield et al (Pub. No.: US 2002/0091320).

Regarding claim 13, Groner et al don't teach presenting output data as an image of vasodilatation or vasoconstriction, colored or shaded according to a scale.

With regards to vasodilation and vasoconstriction; Applicant discloses administer vasoactive agents such as acetylcholine, sodium nitroprusside, determine the effect on microcirculation and output data matrix as an image of vasodilation and vasoconstriction [see 0011, specification].

Accordingly, Shih discloses display different conditions in the microcirculation of human body, such as dilatation, blood cell aggregation, and blood velocity in capillaries; so that microcirculation at multiple areas in human body can be continuously observed and quantitatively measured [see column 3 lines 34-45].

Nonetheless, Crutchfield et al teach administering vasoactive drug and used an assessment method such as calculating a pulsatile index to determine the effect of the drug and condition of a blood vessel [see 0056-0060, 0080, 0192]. Crutchfield et al also teach the presence of vasodilators and/or vasoconstrictors in a patient indicating dilation

or constriction of an artery [see 0218]. Crutchfield et al further teach processing method that can use color coded to display blood flow characteristics such the presence of a blockage or restriction, or the passage of an embolus through the artery [see 0184].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Groner et al with Shih and Crutchfield et al by using color coding to display an image of dilation or constriction after administering vasoactive drug as taught by Crutchfield et al and according to a scale; for the purpose of diagnosing blood flow with accuracy and with an increased visualization.

1. Claims 16-18 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groner et al (US Pat: 5,983,120) stand alone or in view of Shih (US Pat: 6,061,176) in view of Godik (US Pat: 5,699,797) and further in view of Nilsson (US Pat: 5,361,769) and Zinser et al (US Pat: 5,620,000) as applied to claim 12 above and further in view of Nakakuki (Pub. No.: US 2004/0208393).

Regarding claim 17, Groner et al don't mention matrix employing difference of values of matrix representing red and green divided by the sum of corresponding values of data matrix representing red and green.

However, Nakakuki teaches the image data corresponding to red, green and blue may be divided into a group of pixels in a matrix [see 0024] and the luminance for each pixel may be represented as 8-bit data. In this case, the luminance of each pixel in the image data is converted into a numerical value on a scale of 0-255 [see 0024].

Therefore, one with ordinary skill in the art at the time the invention was made would have motivated to combine Groner et al with Nakakuki by using the above teaching of Nakakuki; for the purpose of increasing visualization.

Regarding claims 16, 18 and 36-38, Groner et al don't teach normalization of values of data matrixes and compensating for tissue color.

With regards to normalization of data matrixes and compensating for tissue color; Applicant discloses normalization of the color data matrixes by dividing each color value in the original data matrixes by the average value for the same color representation in the reference area, thereby compensating for fluctuations in flash or continuous light intensity [see 0032, specification].

Accordingly, Nakakuki teaches the image data corresponding to red, green and blue may be divided into a group of pixels in a matrix [see 0024].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Groner et al with Nakakuki by dividing each color value by the average value of the same color representation and any combination thereof to compensate for tissue colors; for accuracy and reliability purposes.

2. Claim 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Groner et al (US Pat: 5,983,120) stand alone or in view of Shih (US Pat: 6,061,176) in view of Godik (US Pat: 5,699,797) and further in view of Nilsson (US Pat: 5,361,769) and Zinser

et al (US Pat: 5,620,000) as applied to claim 12 above and further in view of Takahashi et al (US Pat: 4,366,529).

Regarding claim 19, Groner et al don't teach flexible optical fibers capable of directing light to a body cavity.

Nonetheless, Takahashi et al teach an illuminating light beam is directed to a portion of the body cavity to be examined through a bundle of optical fibers incorporated in the flexible pipe [see column 1 lines 17-27].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Groner et al with Takahashi et al by using flexible fiber optics to direct light into a body cavity; in order to minimize thermal damage to the body cavity which may be caused by the illumination.

Response to Arguments

3. Applicant's arguments with respect to claims 12-22 and 36-38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tse Chen can be reached on (571)272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3777

/Tse Chen/
Supervisory Patent Examiner, Art Unit 3777